

REMARKS

Claims 40-42, and 50-60 are currently pending to which the Examiner has maintained a rejection and presented a new rejection:

- I. Claims 40-42 and 50-56 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Wenk et al., *J. Neurosci.* 14:5986-5995 (1994).
- II. Claims 40-42 and 50-56 are rejected under 35 U.S.C. § 112 ¶ 2 as allegedly being indefinite.

I. The Claims Are Not Anticipated, Inherently, Or Otherwise

A. Anticipation Standards

1. Explicit Anticipation

As the Examiner is well aware, a single reference must disclose each limitation of a claim in order for that reference to anticipate the claim. *Atlas Powder Co. v. E.I. du Pont De Nemours & Co.*, 224 U.S.P.Q. 409, 411 (Fed. Cir. 1984). This criterion is not met with the Wenk et al. reference. Further, the Examiner is reminded that, as method claims, all claim terms (functional and otherwise) must be given full patentable weight.

2. Inherent Anticipation

The Examiner is also well aware that inherent anticipation requires the following:

... [i]n relying upon the theory of inherence, the examiner must provide a basis in fact/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.

MPEP §2112, quoting In re Robertson, 169 F.3d 743 (Fed. Cir. 1999)(emphasis in original).

B. The Claims Are Not Explicitly Anticipated By Wenk et al.

1. “Univariate Z Score”

As explained in the previous Office Action response, the Applicants argued that the Examiner has not recognized novelty regarding a multivariate outcome measurements comprising univariate Z scores. The Applicants herein incorporate by reference the arguments presented in the previous Office Action response.

Interestingly, the Examiner clearly admits that the Applicants teach “univariate Z scores”:

... the Applicant’s multivariate outcome measurement comprise univariate Z scores ...

Final Office Action, pg 2. But the Examiner never provides any rebuttal evidence by showing an explicit teaching within Wenk et al. that teaches one having ordinary skill in the art to create a “univariate Z score”. Under these circumstances, the Examiner has not created a *prima facie* case of anticipation. Based upon this alone, the Applicants respectfully request that the Examiner withdraw the present rejection.

2. “Multivariate Outcome Measurement”

The Examiner has not pointed to any specific measurement(s) within Wenk et al. that represent a “multivariate outcome measurement” as defined by the Applicants, or otherwise understood by one having ordinary skill in the art. The Examiner is reminded that an Applicants’ claims must be viewed “in light of the specification”:

Claims of a patent application ‘are to be construed in the light of the specification and the understanding thereof by those skilled in that art to whom they are addressed’.

Application of Salem, 553 F.2d 676, 683, 193 USPQ 513 (CCPA 1977) (quoting *In re Myers*, 410 F.2d 420, 425 (CCPA 1969) with emphasis added in *Salem*). The Applicants submit that the Examiner has not fulfilled this burden even though the previous Office Action response provided a clear and unambiguous definition for this term. This definition is re-presented for the Examiner’s convenience:

[0045] “Multivariate outcome measurements” are quantitative output measurements collected from **combinations** of univariate neurophysiologic measurements collected from various regions of the brain.

Applicant’s Specification Publication Number 2004/0059241 [emphasis added]. The Examiner has not shown how, or where, Wenk et al. combines univariate neurophysiologic measurements (i.e., for example, Z scores) from various regions of the brain to produce a multivariate outcome measurement. The Applicants have found the Wenk et al. does not even use the term “multivariate”. Based upon this alone, the Applicants respectfully request that the Examiner withdraw the present rejection.

C. The Claims Are Not Inherently Anticipated By Wenk et al.

The Examiner has attempted to explain that Wenk et al. allegedly “inherently anticipates” the Applicants’ claims by stating that:

Thus, it is recognized (inherent) that various measures are taken to obtain the multivariate values because throughout the Wenk et al. document, multiple data is obtained for the subjects during various tests ... (page 5987 “T-maze alternation test”) (page 5987-5988, “Step-through avoidance testing) ... and ... (page 5988, “Electrophysiology”). ... Thus, based upon the fact that various outcome measurements are obtained that involve obtaining multiple data at the same and different points, it is inherent that multivariate outcome measurements are encompassed by Wenk et al.

Final Office Action, pg. 3-4. The Examiner has erred in at least two very fundamental respects.

First, the Examiner has failed to realize that “multivariate outcome measurements” are based upon a mathematical combination of measurements into a single value that are qualitatively similar, but quantitatively different (i.e., for example, “... a combination of univariate neurophysiological measurements, *supra*). The Applicants’ above definition of “multivariate outcome measurement” makes that very clear. For the Examiner’s proposition to be valid (which it is not), Wenk et al. would need to teach that the measurements taken from the “T-maze alternation test” and “Step-Through Avoidance Test” be quantitatively combined with the “Electrophysiology Test” to create a single value. Wenk et al. does not teach, or infer, this type of data analysis. On the contrary, Wenk et al. presents the results from each test independently. Specifically, the “T-Maze” data is presented in Figure 1 presenting a non-continuous raw score data set expressed as “Choice Accuracy” against “Day of Testing”; the Step-Through Avoidance Test” data is presented in Table I presenting a continuous raw score data set expressed as “seconds latency to enter the dark compartment”; and the “Electrophysiology Data” is presented in Figure 2 presenting a continuous raw score data set expressed as “total power expressed as μV^2 ”. Wenk et al. has not presented any suggestion that these qualitatively different raw score measurements could, or should, be

combined and the Examiner (alone) is not qualified to state that there is a suggestion.¹ Instead, Wenk et al., individually discusses the impact of each specific test on assessing cholinergic neuron destruction:

The results from the T-maze task in the present study are consistent with previous reports that suggest the destruction of NBM cholinergic cells is not sufficient to impair performance in this task ...

Wenk et al. pg 5990 rhc – 5991 lhc, and

The results from the avoidance experiments suggest that destruction of NBM cholinergic cells is not sufficient to impair passive avoidance acquisition or retention.

Wenk et al. pg. 5991 rhc, and

... the selective loss of NBM cholinergic cells was not associated with a significant slowing of EEG activity.

Wenk et al. pg 5992 rhc. This independent discussion of the individual test results makes it clear to one having ordinary skill in the art that Wenk et al. at no time considered combining the separate raw data sets into a “multivariate outcome measurement” by using “univariate Z scores”.

Second, the Examiner has failed to take into account that “inherent anticipation” has been held under long standing patent law to require that the claimed element “necessarily flows” from the prior art teachings (*supra*). Clearly, Wenk et al. displays otherwise, as none of the disclosed tests require using “univariate Z scores” to collect or analyze the data sets. Consequently, one having ordinary skill in the art would understand that the tests used in Wenk et al. do not “necessarily” have to use “univariate Z scores”.

¹ The Examiner is not qualified as one having ordinary skill in the art. *In re Rijckaert*, 9 F.3d 1531, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993) (“[T]he examiner’s assumptions do not constitute the disclosure of the prior art.”).

The Applicants respectfully request that the Examiner withdraw the present rejection.

II. The Claims Are Definite

The Examiner states that:

The claims as written are ambiguous because of the phrase ‘under conditions such that said difference determines said medication efficacy’. In particular, ... what particular conditions Applicant is referring to ...

Final Office Action, pg. 5 ¶ 5 [emphasis in original]. The Applicants disagree. Nonetheless, without acquiescing to the Examiner's argument but to further the prosecution, and hereby expressly reserving the right to prosecute the original (or similar) claims, Applicants have amended Claims 40 and 54 to recite that medication efficacy may be determined by “a differential change between said first and second measurement, having support in the Applicants’ Specification, for example:

Medications produce differential changes in the quantified neurophysiological information that are measured across physiologic brain imbalances ...

Applicants’ Specification pg 10 ln 4-6. This amendment is made not to acquiesce to the Examiner's argument but only to further the Applicants' business interests, better define one embodiment and expedite the prosecution of this application.

The Applicants respectfully request that the Examiner withdraw the present rejection.

CONCLUSION

The Applicants believe that the arguments and claim amendments set forth above traverse the Examiner's rejections and, therefore, request that all grounds for rejection be withdrawn for the reasons set above. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, the Applicants encourage the Examiner to call the undersigned collect at 617.984.0616.

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